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EXAMINER

LLOYD, EMILY M

ART UNIT	PAPER NUMBER
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3736

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/551,280	Applicant(s) YAZAKI ET AL.	
	Examiner EMILY M. LLOYD	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>20050927 and 20080702</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

2. Claim 13 is objected to because of the following informalities: claim 13 "the detection of a predetermined component of said humor" lacks antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2-5, 7, 8 and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 2 and 7, it is unclear if this limitation requires that the "detection part provided at said main frame part" (from claim 1) is "at" or directly on the convex part, or if this claim is intended to describe the "overlapped relationship... in plan view" of claim 1, which would not require the convex part and detection part to touch. Further, it is unclear from the language of claims 2 and 7 if the convex part is provided at a position relative to the detection part, or if, instead, the detection part (which seems to

be the movable/replaceable part) is provided/moved to a position corresponding to the convex part of the main frame part.

Regarding claims 3-5, 7 and 17-19, it is unclear if the recitations of a "first humor transfer channel opening" and the "first humor transfer channel" are to the same element or different elements. The Examiner notes that it is unclear if "opening" should be "that opens to" or that "connects to" instead of a structural opening or hole. Claims 5 and 19 are rejected as ultimately depending on claim 3 or 17. The Examiner additionally notes that claim 10 appears to more clearly define what Applicant is intending to claim.

Regarding claim 8, it is unclear what steps are involved in the claimed process. See MPEP 2173.05(q) "Use" Claims.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A "use" claim does not define a proper process. See MPEP 2173.05(q) "Use" Claims.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3, 4 and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent 3734095 (Santomieri).

Regarding claim 1, Santomieri discloses a humor sampling implement (Figures 1-3, 6 and 7) comprising: a main frame part having a humor transfer channel (needle 86 Figures 2, 3, 6 and 7) provided to collect humor through a humor inflow port (distal end of needle 86) and transfer said humor to a humor outflow port (opening 112 Figure 6); and, a detection part provided at said main frame part to detect a predetermined component of said humor transferred through said humor transfer channel (chamber 110 provides for determining if blood is present to indicate "a successful venipuncture" (Column 5 lines 13-16); wherein said main frame part is provided with a convex part (nub 122 Figure 7) arranged so as to be in overlapped relationship with said detection part in plan view (chamber 110 is above nub 122 such that they are overlapping in a plan view) and protruding in said humor transfer channel toward said humor outflow port (nub 122 points upwards toward opening 112).

Regarding claim 3, Santomieri discloses the humor sampling implement as set forth in claim 1, wherein said humor transfer channel comprises a first humor transfer channel opening to said humor inflow port (distal end of needle 86), and a second humor transfer channel connected to said first humor transfer channel (portion of needle 86 proximal to/above nub 122 Figure 7), said second humor transfer channel being different from said first humor transfer channel in a direction of humor transfer in which said humor is transferred along the humor transfer channel (Figure 7); and said convex

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part is provided at an end portion on a humor outflow port side of said first humor transfer channel of said main frame part so as to protrude in said second humor transfer channel (Figure 7).

Regarding claim 4, Santomieri disclose the humor sampling implement as set forth in claim 3, wherein the direction of humor transfer in said first humor transfer channel and the direction of humor transfer in said second humor transfer channel are substantially orthogonal to each other (Figure 7).

Regarding claim 9, Santomieri discloses a method of humor sampling, comprising: collecting humor (Column 5 lines 13-16) through a humor inflow port (distal end of needle 86) of a main frame part of a humor sampling implement (Figures 1-3, 6 and 7); and introducing the humor collected at the humor inflow port to a humor transfer channel (body of needle 86) and transferring the humor along the humor transfer channel to a humor outflow port (opening 112 Figure 6); the main frame part comprising a projection protruding in said humor transfer channel toward said humor outflow port (nub 122 Figure 7 is upward towards opening 112).

Regarding claims 10-12, Santomieri discloses the method as set forth in claim 9, wherein the transfer of the humor along the humor transfer channel comprises transferring the humor collected at the humor inflow port along a first humor transfer channel which opens to said humor inflow port (portion of needle 86 between its distal end and nub 122) and transferring the humor along a second humor transfer channel which is connected to said first humor transfer channel and which is orthogonally

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oriented relative to the first humor transfer channel (portion of needle 86 proximal/above nub 122 Figure 7).

8. Claims 1, 9, 13-15, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6083460 (Morikawa et al.).

Regarding claim 1, Morikawa et al. disclose a humor sampling implement comprising: a main frame part (52 see especially Figure 3) having a humor transfer channel (520) provided to collect humor through a humor inflow port (523) and transfer said humor to a humor outflow port (527 as well as 526 and 55; one of ordinary skill in the art could also interpret the area below 53 as an outflow port); and, a detection part (53) provided at said main frame part to detect a predetermined component of said humor transferred through said humor transfer channel (test paper 53); wherein said main frame part is provided with a convex part arranged so as to be in overlapped relationship with said detection part in plan view and protruding in said humor transfer channel toward said humor outflow port (the curves of 52 between 54 and 55 and pointing towards 532 meet these limitations).

Regarding claim 9, Morikawa et al. disclose a method of humor sampling, comprising: collecting humor through a humor inflow port (523 see especially Figure 3, see also entire document) of a main frame part (52) of a humor sampling implement (see entire document, including Figure 3); and introducing the humor collected at the humor inflow port to a humor transfer channel (520) and transferring the humor along the humor transfer channel to a humor outflow port (527 as well as 526 and 55; one of ordinary skill in the art could also interpret the area below 53 as an outflow port); the

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main frame part comprising a projection protruding in said humor transfer channel toward said humor outflow port (the curves of 52 between 54 and 55 and pointing towards 532).

Regarding claim 13, Morikawa et al. disclose the method of claim 9, wherein the detection of a predetermined component of said humor transferred through said humor transfer channel comprises supplying said humor that has been transferred to the humor outflow port to a test paper which overlies said projection (humor is transferred to test paper 53, see entire document).

Regarding claim 14, Morikawa et al. disclose a humor sampling implement comprising: a main frame part (52 see especially Figure 3, see also entire document) provided with a humor inflow port (523), a humor outflow port (527 as well as 526 and 55; one of ordinary skill in the art could also interpret the area below 53 as an outflow port) and a humor transfer channel (520) extending between the humor inflow port and the humor outflow port; the main frame comprising a projection provided along said humor transfer channel (the curves of 52 between 54 and 55 and pointing towards 532) to at least prevent an increase in a cross-sectional area of a portion of the humor transfer channel between the projection and the humor outflow port (the cross-section of 54 narrows as it approaches this curve); and a test paper (53) provided at said main frame to absorb at least some of the humor supplied to the humor outflow port and detect a component in the humor (test paper 53 is for absorbing humor and detecting a component in the humor, see entire document).

Regarding claim 15, Morikawa et al. disclose the humor sampling implement as set forth in claim 14, wherein the projection possess a configuration such that a cross-sectional area of the projection decreases toward the humor outlet port (the cross-section of the curves of 52 between 54 and 55 and pointing towards 532 decrease in a direction towards 53 and 532).

Regarding claim 17, Morikawa et al. disclose the humor sampling implement as set forth in claim 14, wherein the humor transfer channel comprises a first humor transfer channel (520) opening to the humor inflow port (523) and a second humor transfer channel connected to the first humor transfer channel (54; could also be 55), the second humor transfer channel being oriented at an angle other than zero degrees relative to the first humor transfer channel (Figure 3).

Regarding claim 18, Morikawa et al. disclose the humor sampling implement as set forth in claim 17, wherein the projection is provided at an end portion of the first humor transfer channel (520 and 54) and protrudes into the second humor transfer channel (the cross-section of the curves of 52 between 54 and 55 and pointing towards 532 protrudes into second humor transfer channel 55).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santomieri.

Regarding claim 5, Santomieri does not disclose expressly that $V1/V2$ is in a range of from 0.04 to 0.7, where $V1$ is a volume of said convex part, and $V2$ is an inside volume of said second humor transfer channel. Instead, Santomieri is mute as to the volumes of these components.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide the claimed volume ratio

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because Applicant has not disclosed that the volume ratio provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Santomieri's device, and applicant's invention, to perform equally well with either the setup taught by Santomieri or the claimed volume ratio because both devices would perform the same function of collecting a body fluid equally well.

Therefore, it would have been prima facie obvious to modify Santomieri to obtain the invention as specified in claim 5 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Santomieri.

Regarding claim 6, Santomieri discloses the humor sampling implement as set forth in claim 1. Santomieri does not expressly disclose that said main frame part has a lower member, and an upper member which is positioned on said lower member and which, together with said lower member, defines a part of said humor transfer channel. However, the Examiner notes that it is obvious to make parts/components separable (MPEP 2144.04 V C Making Separable) which could provide, for example, easier and more cost effective manufacturing of the main frame. Additionally, the Examiner notes that it is well known in the art of fluid sampling to assemble a main frame part with an upper and lower member to form a channel.

13. Claims 6, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morikawa et al.

Regarding claim 19, Morikawa et al. disclose the humor sampling implements as set forth in claim 17. Morikawa et al. do not disclose expressly that $V1/V2$ is in a range of from 0.04 to 0.7, where $V1$ is a volume of said convex part, and $V2$ is an inside volume of said second humor transfer channel. Instead, Morikawa et al. are mute as to the volumes of these components.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide the claimed volume ratio because Applicant has not disclosed that the volume ratio provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Morikawa et al.'s device, and applicant's invention, to perform equally well with either the setup taught by Morikawa et al. or the claimed volume ratio because both devices would perform the same function of collecting a body fluid equally well.

Therefore, it would have been prima facie obvious to modify Morikawa et al. to obtain the invention as specified in claim 19 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Morikawa et al.

Regarding claims 6 and 16, Morikawa et al. disclose the humor sampling implements as set forth in claims 1 and 14. Morikawa et al. do not expressly disclose that said main frame part has a lower member, and an upper member which is positioned on said lower member and which, together with said lower member, defines a part of said humor transfer channel. However, the Examiner notes that it is obvious to

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make parts/components separable (MPEP 2144.04 V C Making Separable) which could provide, for example, easier and more cost effective manufacturing of the main frame.

Additionally, the Examiner notes that it is well known in the art of fluid sampling to assemble a main frame part with an upper and lower member to form a channel.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LLOYD whose telephone number is (571)272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd

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Examiner
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/EML/

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736